

Translation

PATENT COOPERATION TREATY

PCT/CH2003/000240



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1937/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CH2003/000240	International filing date (day/month/year) 11 April 2003 (11.04.2003)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC A61F 2/44		
Applicant MATHYS MEDIZINALTECHNIK AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20 September 2004 (20.09.2004)	Date of completion of this report 28 April 2005 (28.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-9 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____ 1-15 _____, filed with the letter of _____ 01 April 2004 (01.04.2004)
- ☒ the drawings:
 pages _____ 1/4-4/4 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☐ claims Nos. _____

because:

☒ the said international application, or the said claims Nos. 15
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental box

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

**Non-establishment of opinion with regard to novelty,
inventive step and industrial applicability**

Claim 15 of the present application defines a method for fixing an implant inside an intervertebral space. This method represents a method for the treatment of the human body by surgery within the meaning of PCT Rule 67.1(iv). Consequently, no examination was carried out for these claims (PCT Article 34(4)(a)(i)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-14	YES
	Claims		NO
Inventive step (IS)	Claims	1-14	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following document:

D1: US-A1-2002/138142 (NICHOLS DAVID ET AL)
26 September 2002 (2002-09-26).

Document D1 is considered to be the closest prior art for the subject matter of claim 1. D1 discloses (the references in parentheses are to D1):

an intervertebral implant comprising two anchoring means (end caps, paragraph 44) for fixing said intervertebral implant to the end plates of a vertebra.

Each anchoring means comprises (see D1, paragraph 35 and figure 6)

- an anchoring part (640) which comprises a central axis (A) and two end faces extending transversely to the central axis (A),
- a plurality of spikes (652) projecting from one end face,
- a through cavity (646) extending parallel to the central axis, and

- fixing means (644a, 644b) by means of which the anchoring part can be detachably locked to the intervertebral implant.

The subject matter of claim 1 differs therefore from the known intervertebral implant in that

the intervertebral implant comprises at each end a terminal plate which intersects the central axis, and in that the terminal plates can be guided through the cavity of the respective anchoring parts.

The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

The problem addressed by the present invention can therefore be considered that of obtaining an intervertebral implant in which the anchoring means can be pressed in a simple manner into the end plates of the vertebra only after the implant has been introduced into the intervertebral space.

The subject matter of claim 1 solves this problem in that the anchoring means can be pushed upwards and downwards against the end plates of the vertebra from the centre of the (e.g., cylindrical) implant after implantation. The anchoring means are directly accessible from the outside.

This solution is neither disclosed nor suggested by the documents cited in the international search report, and therefore claim 1 complies with the requirements of PCT Article 33(2).

Claims 2-14 are dependent on claim 1 and therefore likewise meet the PCT requirements for novelty and inventive step.

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Observations:

The two-part form of claim 1 does not take proper account of the prior art (D1) in accordance with PCT Rule 6.3(b).

The description does not cite document D1 or indicate the relevant prior art disclosed therein (PCT Rule 5.1(a)(ii)).